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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
09/742,008	VISKOV, CHRISTIAN	
Examiner	Art Unit	
Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-21,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-13 and 24 is/are rejected.
- 7) ☒ Claim(s) 4 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 3-21, 23 and 24 are pending.

Applicants' amendment filed December 14, 2005 is acknowledged. Applicants' response has been fully considered. Claims 1, 4, 8, 13, 14 and 23 have been amended, claims 2 and 22 have been cancelled, and a new claim 24 has been added. Claims 15-21 are non-elected invention and withdrawn from consideration. Therefore, claims 1, 3-14, 23 and 24 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claims 4, 14 and 23 is withdrawn in view of applicants' amendment to the claim, and applicant's response at page 28 of the amendment filed December 14, 2005.

### **Withdrawn Claim Rejections - 35 USC § 112**

3. The previous rejection of claims 1-13 and 22, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at pages 29-30 in the amendment filed December 14, 2005.

### ***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 5-13 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 5-13 and 24 are directed to a process for preparing a polyanion for use as an intermediate in the preparation of a cyclosporin derivative, the process comprising treating a cyclosporin with a hexamethyldisilazane metal salt and a metal halide, or a process for preparing a cyclosporin derivative substituted at the 3-position, said process comprising preparing a polyanion by treating a cyclosporin with a hexamethyldisilazane metal salt, optionally in the presence of a metal halide, adding an electrophilic agent to said treated cyclosporin, and, optionally converting the product of said addition to a salt. While the specification indicates the present invention provides a process of preparing a polyanion by treatment of a cyclosporin with a hexamethyldisilazane metal salt, optionally in the presence of a metal halide, which results in cyclosporin derivatives modified at the 3-position with a markedly improved yield and the reaction is carried out at a higher temperature and with lower excess of electrophile (pages 2-3), the specification does not disclose a genus of variants for cyclosporin derivatives prepared via polyanion intermediates.

The specification discloses cyclosporin A derivatives having various substituents at 3 position prepared by reacting a polyanion containing an anion at sarcosine of 3 position with an electrophilic agent (Examples 1-4). However, the specification does not describe preparing any other cyclosporin derivatives, which are not cyclosporin A derivatives and do not contain sarcosine at 3 position. Furthermore, the specification does not disclose any cyclosporin derivatives having various substituents at different positions. Without guidance on the

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preparation of cyclosporin polyanions at different positions, one skilled in the art would not know at what position the substituent occurs in the cyclosporin derivatives, and whether the cyclosporin derivatives are functional. The lack of description on the structures of various cyclosporin polyanions, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite because the claim recites  $-NG_1G_2$  and formula (v), but the claim does not define  $G_1$ ,  $G_2$  and  $G_3$ . Claim 14 is also an improper dependent claim because the claim is dependent from both claims 13 and 4.

### ***Claim Objection***

6. Claims 4 and 23 are objected to because the claims depend from a rejected claim.

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***Conclusion***

7. Claims 1, 3, 5-13 and 24 are rejected; and claims 4 and 23 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

February 24, 2006